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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12-0010]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The National Birth Defects Prevention Study (NBDPS) - (0920-0010, Expiration 06/30/2012) - Extension - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serves as an early warning system for new Teratogens. In 1997, the Birth Defects Risk Factor Surveillance (BDRFS) study, a case-control study of risk factors for selected birth defects, became the National Birth Defects Prevention Study (NBDPS). The major components of the study did not change.

The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth defect surveillance registries in nine states, including metropolitan Atlanta. Control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. The interview takes approximately one hour. A maximum of thirty-six hundred interviews are planned, 2,700 cases and 900 controls, resulting in a maximum interview burden of approximately 3,600 hours for all Centers.

Parents are also asked to collect cheek cells from themselves and their infants for DNA testing. The collection of cheek cells by the mother, father, and infant is estimated to take about 10 minutes per person. Each person will be asked to rub 1 brush inside the left cheek and 1 brush inside the right cheek for a total of 2 brushes per person. Collection of the cheek cells takes approximately 1-2 minutes, but the estimate of burden is 10 minutes to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the cheek cells is 1,800 hours for all Centers.

Information gathered from both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years.

There are no costs to the respondents other than their time. The total estimated annualized burden is 5,400 hours.

Estimated Annualized Burden Table

Type of Respondents	Form Name	Number of Respondents	Number of responses per respondent	Avg. burden per response (in hours)
Mothers	NBDPS mother questionnaire	3,600	1	1
Mothers, fathers, infants	Cheek Cell Specimen Collection	10,800	1	10/60

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